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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,971	07/21/2003	Gerald J. Roth	1/1374	5344

28501 7590 07/05/2005

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EXAMINER	
BERNHARDT, EMILY B	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,971	ROTH ET AL.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,6 and 8* is/are allowed.

6)☒ Claim(s) *2-5,7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 2-5 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 2-5 appear to be substantial duplicates of one another since from a reading of the specification the **same** compound is being employed only variously characterized and there is nothing in the specification that shows how the data changes the scope of the respective compound claims.

2. There is no art-recognized disorder known as "treating excessive or abnormal cell proliferation". Such a phrase is generally used to denote a causative factor in determining the process by which a particular disease occurs. Determining whether a given disease responds or not to excessive or abnormal cellular proliferation involves much experimentation since a negative response from one patient does not mean the drug isnt useful as no drug has 100% effectiveness. Thus what "success rate" determines if a particular compound is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, par.two is whether applicants have clearly defined "their" invention not what may be discovered by future research as this type of claim language clearly requires.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for one metabolite described on p.11, does not reasonably provide enablement for any and all metabolites. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim Identifying a metabolite requires knowledge of degradation pathways of instant compound *in vivo* and nothing short of extensive testing (none identified) would be needed to determine if additional derivatives exist. Also not all metabolites are necessarily active themselves and thus such a scope as literally claimed herein is nonenabled.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Note the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a), August 2000 edition, which includes factors such as the following:

1.) Breadth of the claims-The uses covered by the claim language are vast. It not only covers all cancers in general but also disorders such as psoriasis,

restenosis, glomerular nephritis, pulmonary fibrosis, macular degeneration and rheumatoid arthritis.

2.) Nature of the Invention and level of predictability in the art- The invention is pharmaceutical in nature involving inhibitory activity against several types of tyrosine kinases as set forth in the specification on p.2. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved" and physiological activity is generally considered to be unpredictable. See In re Fisher 166 USPQ 18.

3) Direction or guidance- There is no dosage range informationprovided much less directed to a specific disease.

4) Working examples- No test data has been actually presented for the one species claimed only mention that it has an inhibiting effect on various kinases some which are identified. Thus in the absence of animal studies and in the absence of any correlation between studies conducted **in vitro** and the diseases to be treated, there is no sufficient evidence to support the claimed uses.

5.) State of the Prior Art and level of skill in the Art- While there are many different type of compounds that act as tyrosine kinase inhibitors, there is no evidence in the recent art that one compound is a broad-based antitumor agent much less useful against other types of disorders which result from abnormal cell

proliferation as outlined above. Note the recent publication,Traxler, provided by the examiner, for compounds having gone more testing than that described herein have limited applications against certain types of cancers but not all. Also note Burke for the notion that assaying compounds for TK inhibition for treating cancers and other uses is not art-recognized as predictive of *in vivo* efficacy. See concluding section in the 1994 publication regarding proliferative diseases.

In view of the above considerations, this rejection is being applied.

Claims 1,6 and 8 are allowed over the art of record. WO'081 the closest since it describes the instant compound in the free form does not teach the instant salt form, namely the mono**ethane**sulfonate form. Additionally, specification describes salt form as being less hygroscopic, more soluble and less prone to polymorphism.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

E Bernhardt

Emily Bernhardt
Primary Examiner
Art Unit 1624